

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 11-15-94 OUT 2-6-95

Reviewed by Michael Nzeves Date 2-6-95

EPA Reg. No. or File Symbol 10492-4

EPA Petition or EUP No. None

Date Division Received 10-5-94

Type Product Disinfectant Towelettes

MRID No(s) None

Product Manager M. Swindell (PM 31)

Product Name Isotex 70 Disinfecting Towelletes

Company Name Palmero Health Care

Submission Purpose The registrant is requesting the addition of herpecidal claims to the label and change in product packaging with modification to the directions for use.

Type Formulation Disinfectant Towelettes

Active Ingredients(s)

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride..... 0.12%

n-alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride..... 0.12%

Isopropyl alcohol..... 63.25%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 10492-4

EPA Petition or EUP No. None

Date Division Received 10-5-94

Type Product Disinfectant Towelettes

MRID No(s) None

Product Manager M. Swindell (PM 31)

Product Name Isotex 70 Disinfecting Towelletes

Company Name Palmero Health Care

Submission Purpose The registrant is requesting the addition
of herpeccidal claims to the label and change
in product packaging with modification to the
directions for use.

Type Formulation Disinfectant Towelettes

200.0 **Introduction:**

200.1 **Uses:**

See attached proposed label dated 10-5-94.

200.2 **Background Information:**

The registrant is requesting the addition of herpecidal claims to the label and change in product packaging with modification to the directions for use.

200.3 **Factors Affecting Amount/Type of Data Required:**

None

201.0 **Data Summary**

None

201.1 **Abstract of Test Reports:**

None

201.2 **Brief Description of Tests:**

No efficacy data was submitted for this amendment. The registrant referred to previously reported data (MRID No. 42574204)

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

202.0 Recommendations

202.1 Efficacy Supported By The Data:

No efficacy data was submitted for this amendment. The registrant refers to MRID No. 425742-4 which was previously accepted. The data in MRID No. 425742-4 appear acceptable to support effectiveness of the product as a virucide against Herpes simplex Type 2 when used undiluted on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 1 minute at 20° C.

203.0 Labeling:

On the front panel, under the product name, change "virucidal" to "virucidal**" and change "herpeccidal" to "herpeccidal***". Use two asterisks to denote the specific virus and herpes species for which efficacy data has been submitted.